

REMARKS

Presently, claims 1-10 are pending and under rejection. Claims 11-36 have previously been withdrawn.

Claim Objections

The Examiner has objected to claims 8-10 for informalities. The above amendments made to the claims address this objection and Applicants respectfully request that this objection be withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph – Written Description

The Examiner has rejected claims 1-10 under 35 U.S.C. §112, first paragraph, "as failing to comply with the written description requirement." The Examiner states that "the claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner characterizes the claims as reading "on any non-transgenic domesticated *L. esculentum* plant having flavonol content in the flesh of the fruit of said plant that is greater than .5µg/mgdwt." For support the Examiner cites MPEP 2163, *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed Cir. 2003) and *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

The Examiner also asserts that the only *Lypersicon* lines that showed flavonol content in the flesh of the fruit were LA1963, LA2884 and LA1926, and goes on to point out that none of these lines were *L. esculentum* plants. Although the Examiner also points out that the specification discloses and describes a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid that possesses the desired flavonol characteristics, the Examiner then states that this plant does not appear to be a non-transgenic domesticated *L. esculentum* plant. Additionally, the Examiner points to a publication by the inventors which stated as follows:

[i]t turned out to be difficult to produce tomatoes from these crosses, and the fruit was invariably seedless...it was not possible to further analyze progeny from the F1 hybrid...a breeding program to remove interspecific breeding barriers between *L. pennellii* and *L. esculentum* is required in order to obtain fertile hybrids for subsequent analysis of the high flavonoid trait in the next generation

(OA 7/16/2007 at 5) The Examiner summarizes that it is unclear how Applicants were in possession of an *L. esculentum* plant with the desired flavonol characteristics because "the prior art teaches that it was not possible to further analyze progeny from the F1 hybrid because of interspecific breeding barriers between *L. pennellii* and *L. esculentum*." (emphasis added)

Applicants respectfully traverse this rejection. Initially, Applicants point out that the publication cited by the Examiner, J. Agric. Food Chem 53: 1231-1236, 2005, was published after this application was filed, yet the Examiner refers to this publication as "prior art". Obviously, with a publication date after the filing date of this application, the publication cannot be considered prior art and should not be cited against Applicants as such. However, Applicants do recognize that as this publication is written by the inventors of this application, some explanation of that statement is necessary.

Applicants submit herewith the declaration of the inventor, Michael G. Willits (hereafter the "Willits Declaration"). In his declaration, Dr. Willits explains that the statement being cited by the Examiner was not made to suggest that the breeding process to obtain an *L. esculentum* from the F1 hybrids with the desired flavonol characteristics was not possible. (Willits Declaration page 3, ¶ 9) In actuality, Dr. Willits states that the *L. esculentum* variety was not created from the F1 hybrids because they reached the end of their project and there was neither the funding nor the facilities to proceed with the development of a breeding program. (Willits Declaration page 3, ¶ 9) Dr. Willits and his group of researchers produced a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid, which demonstrated the transfer of the desired flavonol trait to the hybrid tomato fruit. (Willits Declaration page 3, ¶ 10) In the context of the publication, the term "very difficult" referred only to this trait and not to the overall breeding process. (Willits Declaration page 3, ¶ 10)

Dr. Willits goes on to state that the creation of an *L. esculentum* variety maintaining the production of flavonoids in the fruit could be accomplished by any competent breeder within well known, standard "ordinary skill in the art" breeding methods. (Willits Declaration page 3, ¶ 10) A person of ordinary skill in the art would recognize upon reading of the specification that to obtain the claimed *L. esculentum* plant, they would only need to create a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid, select a progeny with the desired flavonol trait, and then develop a breeding scheme involving standard backcrossing and self-pollination methods to obtain an *L. esculentum* plant with the desired characteristics.

Thus, Applicants submit that the application does show that Applicants were in possession of the claimed invention, as the only remaining steps beyond those specifically described in the specification were conventional, standard breeding processes that would be known to a person of ordinary skill in the art. Applicants respectfully request reconsideration of this rejection.

Rejections Under 35 U.S.C. §102(b)

Claims 1-10 stand rejected under 35 U.S.C. §102(b) as anticipated by Goffreda et al (Theor. Appl. Genet. 78: 210-216, 1989). The Examiner States that "Goffreda discloses a *L. esculentum*

plant having genes introgressed from *L. pennellii* (see page 212, Tables 1-3) and thus, would inherently possess a flavonol content in the flesh of the fruit" as claimed by Applicants. The Examiner bases this assertion on language in the specification which states as follows: "the introduction of the genetic factors from *L. pennellii* into the hybrid plant results in the expression of the flavonol biosynthetic genes and subsequent production of flavonols and flavonol glucosides in the peel and also in the flesh." (see page 14, lines 11-14) The Examiner then states that "the claims are interpreted as any tomato plant having genes introgressed from *L. pennellii*."

Under the standard for §102(b) analysis found in MPEP 2131, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Applicants respectfully traverse this rejection. Applicants do not agree that any *L. esculentum* plant having genes introgressed from *L. pennellii* would inherently possess the claimed flavonol characteristics. In Goffedra, they were trying to introgress resistance to potato aphids from *L. pennellii* into *L. esculentum*. Simply crossing any *L. esculentum* plant with any *L. pennellii* plant would not necessitate that the progeny of that cross would possess the claimed flavonol characteristics, especially when the purpose of the cross is to introgress an entirely different trait without any awareness of whether the trait responsible for the claimed flavonol characteristics is even present. In support of this argument, the declaration Dr. Willits also addresses this rejection.

According to Dr. Willits, the Examiner's statement "that any cross of these two species would inherently possess the flavonol characteristics of your invention" is only true in limited circumstances. For example, if you were aware of this trait and then set up a breeding program to specifically introgress this trait, which is actually determined by two different, unlinked genes. (Willits Declaration page 3, ¶ 12) Thus, in order to create a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid, one would not only need to develop a breeding program that specifically introgresses this trait, but one would need to be aware of it in the first place. According to Dr. Willits, being aware of the trait is not a simple matter. A simple scan of flavonoid production in wild species, including *L. pennellii*, does not identify lines that are suitable to confer the trait. (Willits Declaration page 3, ¶ 13) During the development of the claimed invention, Dr. Willits analyzed the expression of flavonoid pathway genes in the fruit and determined why *L. esculentum* did not make the appropriate flavonoids in the fruit. His group then located a wild line (in this case *L. pennellii*) that would correct the gene expression. (Willits Declaration page 3, ¶ 13) Thus, Applicants submit that obtaining a *L. esculentum* plant with the claimed flavonol characteristics is not something that would be inherent in **any** cross of *L. esculentum* with *L. pennellii*. As the Goffedra reference does not contain each and every element of the claims, and as inherently possessing those traits is not necessarily true, Applicants request that this rejection be withdrawn.

Claims 1-10 also stand rejected under 35 U.S.C. §102(b) as anticipated by Stewart et al (J. Agric. Food Chem. 48: 2663-2669, 2000). The Examiner states that "Stewart et al disclose non-transgenic domesticated *L. esculentum* plants having a flavonol content in the flesh of the fruit of said plant that is greater than .5µg/mgdwt (see page 2667, Table 2).

Applicants respectfully traverse this rejection. Applicants draw the Examiner's attention to the explanation of the data for Table 2 on page 2667. This explanation follows the super script "a" and state as follows: "Data are expressed as µg/g (fw) +/− SE (n=3)." The Examiner should note that the measurements are in µg/gB and not µg/mg. Thus, the level of flavonol for the listed varieties is beneath the .5µg/mgdwt threshold specified in the claims. Therefore, this reference cannot anticipate the claims of the instant application and Applicants respectfully request that this rejection be reconsidered.

CONCLUSION

Applicants respectfully submit that all outstanding issues in the present case have been addressed in this paper. Applicants request continued prosecution on the merits and allowance of the claims as presented herein. In the event issues remain that could be dealt with on the telephone, the Examiner is encouraged to call the undersigned attorney for Applicants at 919-765-5117.

Respectfully submitted,



S. Matthew Edwards
Attorney for Applicants
Reg. No. 55,141
Phone: (919) 765-5117

Syngenta Biotechnology, Inc.
Patent Department
Post Office Box 12257
Research Triangle Park, NC 27709-2257

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